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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,891	03/31/2004	Maurice Arthur Trewhella	GRH0105PUSA	7582

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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,891	TREWHELLA ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 4-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 09, 2008 has been entered. Claims 2-3 have been cancelled and new claims 35-37 have been added. Claims 1, 4-37 are pending in this application. Upon further reconsideration of the application, a new restriction follows below.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

    1. Claim 16, drawn to a method of reducing an organic compound, the method comprising subjecting the organic compound to a yeast-water paste of a yeast mediated reduction in the presence of an amount of water that is sufficient for enzymes to be hydrated but insufficient to provide a visible separate water layer wherein the reduction is conducted in the absence of any additional solvent, wherein water-to yeast ratio is up to 1.5 ml/g, and wherein the organic compound is a compound of Formula I.

    2. Claim 16, drawn to a method of reducing an organic compound, the method comprising subjecting the organic compound to a yeast-water paste of a yeast mediated reduction in the presence of an amount of water

that is sufficient for enzymes to be hydrated but insufficient to provide a visible separate water layer wherein the reduction is conducted in the absence of any additional solvent, wherein water-to yeast ratio is up to 1.5 ml/g, and wherein the organic compound is a compound of Formula II.

3. Claim 16, drawn to a method of reducing an organic compound, the method comprising subjecting the organic compound to a yeast-water paste of a yeast mediated reduction in the presence of an amount of water that is sufficient for enzymes to be hydrated but insufficient to provide a visible separate water layer wherein the reduction is conducted in the absence of any additional solvent, wherein water-to yeast ratio is up to 1.5 ml/g, and wherein the organic compound is a compound of Formula III.

4. Claims 1, 24-33 and 35-37, drawn to a method of reducing an organic compound, the method comprising subjecting the organic compound to a yeast-water paste of a yeast mediated reduction in the presence of an amount of water that is sufficient for enzymes to be hydrated but insufficient to provide a visible separate water layer wherein the reduction is conducted in the absence of any additional solvent, wherein water-to yeast ratio is up to 1.5 ml/g, and wherein the organic compound is a compound of Formula IV.

5. Claim 34, drawn to a product produced by the method of claim 1, wherein the organic compound is compound of Formula I.

6. Claim 34, drawn to a product produced by the method of claim 1, wherein the organic compound is compound of Formula II.

7. Claim 34, drawn to a product produced by the method of claim 1, wherein the organic compound is compound of Formula III.

8. Claim 34, drawn to a product produced by the method of claim 1, wherein the organic compound is compound of Formula IV.

Linking Claims

3. Claims 1, 4-15, 17-23, 31-33, 35-37 link(s) inventions 1-3. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1, 4-15, 17-23, 31-33, 35-37. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting

rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

4. Groups 1-8 are independent and distinct from each other as they are drawn to compounds of formula (I)-(IV). Groups 1 and 5 encompass 1,3 diketone of formula (I), wherein there are multiple variables. Groups 2 and 6 are drawn to epoxy ketone compounds of formula (II), wherein there are multiple variables. Groups 3 and 7 encompass ketone compounds of formula (III), wherein there are multiple variables. Groups 4 and 8 are drawn to alkene compounds of formula (IV), wherein there are multiple variables.

Each of groups 1-4 and 5-8 are directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other two groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the

structure of the prior art would not have been expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in groups 1-8, these inventions are distinct. Note that in accordance with the holding of ***Application of Papesch***, ***50 CCPA 1084***, ***315 F.2d 381***, ***137 USPQ 43 (CCPA 1963)***, and ***In re Lalu***, ***223 USPQ 1257 (Fed. Cir. 1984)***, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

5. Method of Groups 1-4 and Groups 5-8 are independent and distinct from each other as they are drawn to compounds of formula (I)-(IV). Method of Groups 1-4 are drawn to a method of reducing an organic compound, comprising subjecting the organic compound to a yeast-water paste. Inventions 5-8 are drawn to compounds of Formulae (I)-(IV). Inventions 5-8 can be made by material different methods, such as synthesis of these compounds and utilizing the reducing agent, such as sodium, magnesium or copper. Further, search for one would not necessarily lead to the other.

The inventions are distinct, each from the other because of the following reasons:

6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

7. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

8. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

9. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

10. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

12. This application contains claims directed to the following patentably distinct species:

Different compounds of Formula I: due to different generic variables R1, R2, R3 and R4;

Different compounds of Formula II: due to different generic variables R1, R2, R5 and R6;

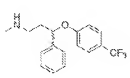
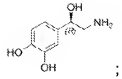
Different compounds of Formula III: due to different generic variables R1, R2, R3 and R7;

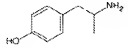
Different compounds of Formula IV: due to different generic variables R8, R9, R10, R11;

Different pharmaceutical produced: from claim 23 for Groups 1-3 or 5-7;

Different pharmaceutical produced: from claim 30 for Group 4 or 8;

13. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Different compounds of Formula I-IV are patentably independent and distinct due to each formula having different structures and functionality within each Group. For example, Formula I has the general formula of 1,3 diketone. There are different variables that lead to different 1,3 diketone structures. Furthermore, each variable is a genus, thus, there are vast numbers of each 1,3 diketone that are possible. Each 1,3 diketone would not necessarily react the same as the other. Formula II has the general formula of epoxy ketone. There are different variables that lead to different epoxy ketones. Furthermore, each variable is a genus, thus, there are vast numbers of each epoxy ketones that are possible. Due to the sterically hindering epoxide structure of the formula, each epoxy ketone would not necessarily react the same as the other. Formula III has the general formula of ketone. There are different variables that lead to different ketones. Furthermore, each variable is a genus, thus, there are vast numbers of each ketone that are possible. Each ketone would not necessarily react the same as the other. Formula IV has the general formula of an alkene. There are different variables that lead to different alkenes. Furthermore, each variable is a genus, thus there are vast numbers of alkenes that are possible. Further search for each 1,3 diketone, epoxyketone, ketone, or alkene would not necessarily lead to the other 1,3 diketone, epoxyketone, ketone, or alkene. Different pharmaceutical produced are patentably independent and distinct due to their different structures. For example, fluoxetine has the structure


; norepinephrine has the structure 
;

hydroxyamphetamine 
. Further, search for one would not necessarily lead to the other.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4-16, 24-25, 31-37 are generic.

15. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

16. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. If Group 1 or 5 is elected, Applicant is required to elect a single disclosed species of Formula I, wherein all of the variables are elected to arrive at a single compound of

Formula I and a pharmaceutical product produced. If Group 2 or 6 is elected, Applicant is required to elect a single disclosed species of Formula II, wherein all of the variables are elected to arrive at a single compound of Formula II and a pharmaceutical product produced. If Group 3 or 7 is elected, Applicant is required to elect a single disclosed species of Formula III, wherein all of the variables are elected to arrive at a single compound of Formula III and a pharmaceutical product produced. If Group 4 or 8 is elected, Applicant is required to elect a single disclosed species of Formula IV, wherein all of the variables are elected to arrive at a single compound of Formula IV and a pharmaceutical product produced. For example, Applicant elects Group 1, elects the compound of Formula I, wherein R1 is unsubstituted phenyl (single aromatic ring), R2, R3 are H, and R4 is pyrrolidino having the structure  , and the pharmaceutical product produced is fluorextine.

18. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

19. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654